



**International
Standard**

ISO 7199

**Cardiovascular implants and
artificial organs — Blood-gas
exchangers (oxygenators)**

*Implants cardiovasculaires et organes artificiels — Échangeurs
gaz/sang (oxygénateurs)*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 7199:2016), which has been technically revised. It also incorporates the Amendment ISO 7199:2016/Amd.1:2020.

The main changes are as follows:

- circular definitions have been corrected for platelet reduction ([3.10](#)), plasma free haemoglobin ([3.11](#)) and white blood cell reduction ([3.12](#));
- the definition of priming volume ([3.18](#)) has been added;
- the sampling time point of 5 min has been deleted in [Table 2](#).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is intended to ensure that devices designed to affect the exchange of gases in support of, or as a substitution for, the normal respiratory function of the lungs have been adequately tested for both their safety and function, and that extracorporeal device characteristics are appropriately disclosed when labelling the device.

This document therefore contains procedures to be used for the evaluation of extracorporeal blood-gas exchangers (oxygenators). Type test procedures to determine the gas transfer, blood cell damage and heat exchanger performance are described, although limits for these characteristics are not specified. Ready identification of the performance characteristics should, however, assist the user in the selection of an oxygenator that suits the needs of the patient.

This document also includes minimum reporting requirements that allow the user to compare performance characteristics of oxygenators of different designs in a standard way.

This document makes reference to other International Standards in which methods for the determination of characteristics common to medical devices can be found.

No provisions have been made for the quantification of microbubble generation or for the non-formed elements of bovine blood because there currently is no consensus regarding satisfactorily reproducible test methods.

Requirements for animal and clinical studies have not been included in this document.

This document contains only those requirements that are specific to oxygenators. Since non-toxicity is anticipated to be the subject of a future horizontal/level 1 standard, this document does not cover non-toxicity.

Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)

1 Scope

This document specifies requirements for sterile, single-use, extracorporeal blood-gas exchangers (oxygenators) intended for the supply of oxygen to, and the removal of carbon dioxide from, human blood, during cardiopulmonary bypass (CPB) for up to 6 h, extracorporeal lung assist [ECLA with veno-venous (VV), veno-arterial (VA) or veno-arterial-venous (VAV) cannulation strategies], cardiopulmonary support (CPS), extracorporeal life support (ECLS with VA cannulation strategy), extracorporeal carbon dioxide removal (ECCO₂R), and other extracorporeal circulation techniques requiring blood-gas exchange.

This document also applies to heat exchangers and arterial filters that are integral parts of the oxygenator.

This document also applies to external equipment unique to the use of the oxygenator.

This document does not apply to

- implanted oxygenators,
- liquid oxygenators,
- extracorporeal circuits (blood tubing),
- separate heat exchangers,
- separate ancillary devices, and
- separate arterial line filters.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 17665, *Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

blood-gas exchanger oxygenator

extracorporeal device designed to supplement, or be a substitute for, the respiratory function of the lungs

3.2

blood pathway

portion of the *oxygenator* (3.1) containing blood during intended clinical use

3.3

gas pathway

portion of the *oxygenator* (3.1) containing the ventilation gas during intended clinical use

3.4

heat exchanger

component that is intended to control the temperature of the circulating blood or priming solution

3.5

heat exchanger performance factor

R

ratio of the difference between the temperature of blood at the outlet of the *oxygenator* (3.1) and the temperature of blood at the inlet of the oxygenator to the difference between the temperature of the water at the inlet of the *heat exchanger* (3.4) and the temperature of blood at the inlet of the oxygenator

3.6

integral arterial filter

component that is intended to filter particles such as blood clots, debris and gas emboli from the blood

3.7

filtration efficiency

ability of the filter to remove particles from the simulated blood suspension test fluid

Note 1 to entry: Filtration efficiency is expressed as a percentage.

3.8

integral part

part that is connected to the *oxygenator* (3.1) and cannot normally be separated by the user

3.9

operating variable

setting of controls that affects the function of the device

3.10

platelet reduction

decrease in platelet count in a circuit incorporating an *oxygenator* (3.1)

Note 1 to entry: Platelet reduction is expressed as a percentage.

3.11**plasma free haemoglobin**

haemoglobin that is released from the red blood cells to the plasma

3.11.1**normalized index of haemolysis****NIH**

mass of *plasma free haemoglobin* (3.11) released after pumping 100 l of blood

$$\text{NIH} = \Delta f_{\text{Hb}} \cdot V \cdot \frac{100 - \text{Hct}}{100} \cdot \frac{100}{Q \cdot t}$$

where

Δf_{Hb} is the increase of plasma free haemoglobin concentration over the sampling time interval, in g/l;

V is the circuit volume, in l;

Q is the flow rate, in l/min;

Hct is the haematocrit, in %;

t is the sampling time interval, in min

Note 1 to entry: The normalized index of haemolysis is expressed in grams per hectolitre.

3.12**white blood cell reduction**

decrease in white blood cell count in a circuit incorporating an *oxygenator* (3.1)

Note 1 to entry: White blood cell reduction is expressed as a percentage.

3.13**residual blood volume**

difference between the priming volume of the unit and the blood volume that can be extracted

3.14**blood analogue**

test solution which simulates certain blood characteristics relevant for testing, such as viscosity and salinity

3.15**subject device**

device under test

3.16**comparator device**

device similar to the *subject device* (3.15) that is a legally marketed device, recognized-to-be-safe and is used for the same intended clinical use

3.17**worst-case condition**

operating variable (3.9) within those specified by the manufacturer for intended clinical use which represents the supposed worst-case device operation for the respective test

3.18**priming volume**

amount of fluid needed to fill the blood path of the device